



Translation

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  DISNALET001	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No.  PCT/IB2003/001295	International filing date (day/month/year)  09 April 2003 (09.04.2003)	Priority date (day/month/year)	
International Patent Classification (IPC) or national classification and IPC  A61K 38/48, 35/78, 7/48, A61P 17/02			
<b>Applicant</b> GOMEZ TORRES, Harold, Armando			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.	
<input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).	
These annexes consist of a total of <u>3</u> sheets.	
3. This report contains indications relating to the following items:	
I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application	

Date of submission of the demand  09 November 2003 (09.11.2003)	Date of completion of this report  18 July 205 (18.07.2005)
Name and mailing address of the IPEA/RU  Facsimile No.	Authorized officer  Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IB2003/001295

## I Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed  
 the description:

pages \_\_\_\_\_ 1-22, 24-34 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_ 23 \_\_\_\_\_, filed with the letter of 09 November 2004 (09.11.2004)

the claims:

pages \_\_\_\_\_ \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_ \_\_\_\_\_, as amended (together with any statement under Article 19)  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_ 35-3- \_\_\_\_\_, filed with the letter of 09 November 2004 (09.11.2004)

the drawings:

pages \_\_\_\_\_ \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the sequence listing part of the description:

pages \_\_\_\_\_ \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_ \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
 the language of publication of the international application (under Rule 48.3(b)).  
 the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority in written form.  
 furnished subsequently to this Authority in computer readable form.  
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/fig \_\_\_\_\_

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/01295
--

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

The examination statement is made on the basis of claims 1 to 11, as amended on 09 November 2004, in the light of the documents cited in the search report:

D1: US 5 024 838 A (1991-06-18)

D2: WO 00/37037 A (2000-06-29)

D3: WO 93/20838 A (1993-10-28)

D4: WO 98/53850 A (1998-12-03)

Document D1 relates to a topical composition in the form of a gel for treating skin, including an antiseptic, sapogenin, a proteolytic enzyme (papain) and a thickening agent (carboxymethylcellulose).

D2 relates to a topical composition in the form of a gel for treating skin burns, including one or more organic acids (acetic acid, citric acid), a plant-based agent, a protective agent (carbopol) and an anaesthetic agent.

D3 relates to a topical composition for treating skin burns and wounds, in the form of a hydrophilic gel or in the form of a gel in combination with a water-soluble polymer, and including a proteolytic enzyme (papain).

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/IB 03/01295

D4 relates to a topical composition for treating skin, including a proteolytic enzyme (papain).

An analysis of the prior art (D1 to D4) shows that it does not include an indication of the composite composition as per amended claim 1. Furthermore, none of the cited documents includes information on the presence of an emulsifier (triethanolamine) and a preservative (methyl paraben and propyl paraben) in therapeutic compositions.

Given that the composition according to claim 1 is not known or obvious and has an effective pain-killing activity as well as protective, wound-healing and anti-inflammatory activities, claims 1 to 9 comply with the requirements of novelty and inventive step. Claims 10 and 11 also comply with the requirements of novelty and inventive step because they refer to claims 1 to 9.

Claims 1 to 11 comply with the requirement of industrial applicability.